UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

OSWER Directive # 9355.4-12

MEMORANDUM

SUBJECT: Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities

FROM: Elliott P. Laws
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TO: Regional Administrators I-X

PURPOSE

As part of the Superfund Administrative Improvements Initiative, this interim directive establishes a streamlined approach for determining protective levels for lead in soil at CERCLA sites and RCRA facilities that are subject to corrective action under RCRA section 3004(u) or 3008(h) as follows:

- It recommends screening levels for lead in soil for residential land use (400 ppm);[1]
- It describes how to develop site-specific preliminary remediation goals (PRGs) at CERCLA sites and media cleanup standards (MCSs) at RCRA Corrective Action facilities for residential land use; and,
- It describes a plan for soil lead cleanup at CERCLA sites and RCRA Corrective Action facilities that have multiple sources of lead.

This interim directive replaces all previous directives on soil lead cleanup for CERCLA and RCRA programs (see the Background section, 1989-1991).

KEY MESSAGES

Screening levels are not cleanup goals. Rather, these screening levels may be used as a tool to determine which sites

[1] The residential screening level is the same concept as the action level proposed in the RCRA Corrective Action Subpart S rule (July 27, 1990, 55 *Federal Register* 30798).

contribution of different environmental sources of lead to overall blood lead levels (e.g., consideration of the importance of soil lead levels relative to lead from drinking water, paint and household dust). It offers a flexible approach to considering risk reduction options (referred to as the "bubble" concept) that allows for remediation of lead sources that contribute significantly to elevated blood lead. This guidance encourages the risk manager to select, on a site-specific basis, the most appropriate combination of remedial measures needed to address site-specific lead exposure threats. These remedial measures may range widely from intervention to abatement. However, RCRA and CERCLA have very limited authority to address interior exposures from interior paint. For a detailed discussion of the decision logic for addressing lead-contaminated sites, see the Implementation section and Appendix A.

Relationship to lead paint guidance. In addition, this interim directive clarifies the relationship between guidance on Superfund and RCRA Corrective Action cleanups, and EPA's guidance on lead-based paint hazards (discussed further in Appendix C). The paint hazard guidance will be issued to provide information until the Agency issues regulations identifying lead-based paint hazards as directed by Section 403 of the Toxic Substances Control Act (TSCA)[2]. Lead-based paint hazards are those lead levels and conditions of paint, and residential soil and dust that would result in adverse health effects.

The two guidance documents have different purposes and are intended to serve very different audiences. As a result the approaches taken differ to some degree. The lead-based paint hazard guidance is intended for use by any person who may be involved in addressing residential lead exposures (from paint, dust or soil.) It thus relates to a potentially huge number of sites, and serves a very broad potential audience, including private property owners or residents in addition to federal or state regulators. Much residential lead abatement may take place outside any governmental program, and may not involve extensive site-specific study.

This OSWER guidance, on the other hand, deals with a much smaller number of sites, being addressed under close federal regulatory scrutiny, at which extensive site characterization will have been performed before cleanup decisions are made. Thus, the RCRA and CERCLA programs will often have the benefit of much site-specific exposure information. This guidance is intended for use by the relatively small number of agency officials who oversee and direct these cleanups.

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[2]Title IV of TSCA (including section 403) was added by the Residential Lead-Based Paint Hazard Reduction Act of 1992 (Title X of the Housing and Community Development Act of 1992).

or portions of sites do not require further study and to encourage voluntary cleanup. Screening levels are defined as a level of contamination above which there may be enough concern to warrant site-specific study of risks. Levels of contamination above the screening level would NOT automatically require a removal action, nor designate a site as "contaminated."

The residential screening level for lead described in this directive has been calculated with the Agency's new Integrated Exposure Uptake Biokinetic Model (IEUBK) model (Pub. # 9285.7-15-2, PB93-963511), using default parameters. As outlined in the Guidance Manual for the IEUBK Model for Lead in Children (Pub. # 9285.7-15-1, PB93-963510, February 1994), this model was developed to: recognize the multimedia nature of lead exposures; incorporate important absorption and pharmacokinetic information; and allow the risk manager to consider the potential distributions of exposure and risk likely to occur at a site (the model goes beyond providing a single point estimate output). For these reasons, this approach is judged to be superior to the more common method for assessing risks of non-cancer health effects which utilizes the reference dose (RfD) methodology. Both the Guidance Manual and the model are available to Superfund staff through the Superfund Document Center (703-603-8917) and to the public through the National Technical Information Service (703-487-4650).

Residential preliminary remediation goals (PRGs) for CERCLA remediations and media cleanup standards (MCSs) for RCRA corrective actions can be developed using the IEUBK model on a site-specific basis, where site data support modification of model default parameters. At some Superfund sites, using the IEUBK model with site-specific soil and dust characteristics, PRGs of more than twice the screening level have been identified. However, it is important to note that the model alone does not determine the cleanup levels required at a site. After considering other factors such as costs of remedial options, reliability of institutional controls, technical feasibility, and/or community acceptance, still higher cleanup levels may be selected.

The implementation of this guidance is expected to provide for more consistent decisions across the country and improve the use of site-specific information for RCRA and CERCLA sites contaminated with lead. The implementation of this guidance will aid in determining when evaluation with the IEUBK model is appropriate and in assessing the likelihood that environmental lead poses a threat to the public. Use of the IEUBK model in the context of this guidance will allow risk managers to assess the

Both the TSCA Section 403 and OSWER programs use a flexible, tiered approach. The OSWER guidance sets a residential screening level at 400 ppm. As noted above, this is not intended to be a "cleanup level" for CERCLA and RCRA facilities, but only to serve as an indicator that further study is appropriate. The Section 403 guidance indicates that physical exposure-reduction activities may be appropriate at 400 ppm, depending upon site-specific conditions such as use patterns, populations at risk and other factors. Although worded somewhat differently, the guidances are intended to be similar in effect. For neither guidance is 400 ppm to automatically be considered a "cleanup level"; instead, it indicates a need for considering further action, but not necessarily for taking action. Neither is meant to indicate that cleanup is necessarily appropriate at 400 ppm. The greater emphasis in this OSWER guidance on determining the scope of further study reflects the fact that both CERCLA and RCRA cleanups proceed in stages with detailed site characterization preceding response actions in every case.

Above the 400 ppm level, the Section 403 guidance identifies ranges over which various types of responses are appropriate, commensurate with the level of potential risk reduction, and cost incurred to achieve such risk reduction. For example, in the range of 400 to 5000 ppm, limited interim controls are recommended depending, as noted above, on conditions at the site, while above 5000 ppm, soil abatement is recommended. This OSWER guidance does not include comparable numbers above 400 ppm; instead, as discussed above, it recommends the site-specific use of the IEUBK model to set PRGs and MCSs, when necessary. The remedy selection process specified in the National Contingency Plan (NCP) should then be used to decide what type of action is appropriate to achieve those goals.

In general, because the Section 403 guidance was developed for a different purpose and audience, OSWER does not recommend that it be used as a reference in setting PRGs and MCSs or in determining whether action at a particular site is warranted. (To put it another way, it generally should not be treated as a "to be considered" document or "TBC" under CERCLA.) The section 403 guidance is meant to provide generic levels that can be used at thousands of widely varying sites across the nation. The detailed study that goes on at CERCLA or RCRA sites will allow levels to be developed that are more narrowly tailored to the individual site. Nothing in the section 403 guidance discourages setting more site-specific levels for certain situations; in fact, it specifically identifies factors such as bioavailability that may significantly affect the evaluation of risk at some sites.

The IEUBK model. The Agency is further studying both the IEUBK model and analyses of epidemiologic studies in order to better develop the technical basis for rulemaking under TSCA

Section 403. The Agency intends to promulgate regulations under Section 403 setting health-based standards for lead in soil and dust. OSWER intends to issue a final soil lead directive once the TSCA Section 403 regulations are finalized. For additional information on TSCA Section 403 developments, call (202) 260-1366.

However, the Agency believes that risk managers (risk assessors, on-scene coordinators, remedial project managers, and other decision-makers at Superfund and RCRA sites) are currently in need of the best guidance available today. The Agency believes that the IEUBK model is the best available tool currently available for assessing blood lead levels in children. Furthermore, use of the IEUBK provides allows the risk manager to consider site-specific information that can be very important in evaluating remediation options. Therefore, using the latest developments in the IEUBK model and the collective experience of the Superfund, RCRA Corrective Action, and TSCA Section 403 programs, the Agency is offering this guidance and is recommending a residential screening level for Superfund and RCRA sites of 400 ppm.

BACKGROUND

Early OSWER guidance (1988-1991). Four guidance documents on soil lead cleanup were issued by OSWER during the period of 1989 to 1991:

1. September 1989, OSWER Directive #9355.4-02. This guidance recommended a soil lead cleanup level of 500 - 1000 ppm for protection of human health at residential CERCLA sites.

2. May 9, 1990. RCRA Corrective Action program guidance on soil lead cleanup. This guidance described three alternative methods for setting "cleanup levels" (not action levels) for lead in soil at RCRA facilities. One approach was to use levels derived from preliminary results of IEUBK model runs. The other two approaches were to use the range of 500 to 1000 provided in the 1989 directive on CERCLA sites, or to use "background" levels at the facility in question.

3. June 1990, OSWER Directive #9355.4-02A. Supplement to Interim Guidance on Establishing Soil Lead Cleanup Levels at Superfund Sites. This memorandum reiterated that the September 1989 directive was guidance and should not be interpreted as regulation.

4. August 29, 1991. This supplemental guidance discussed EPA's efforts to develop a new directive that would

"action" levels set forth in Appendix D of the proposed Subpart S Corrective Action rule. In the July 27, 1990 RCRA proposal (55 Federal Register 30798), EPA introduced the concept of "action levels" as trigger levels for further study and subsequent remediation at RCRA facilities. In this respect, the current directive's "screening levels" are analogous to the proposed rule's "action levels." In the proposal, where data were available, action levels were developed for three pathways of human exposure to contaminants: soil ingestion, water ingestion and inhalation of contaminated air. Exposure assumptions used in the calculations were set out in Appendix D of the proposal. For the soil pathway, action levels were calculated two different ways depending on whether the contaminant in the soil was a carcinogen or a systemic toxicant. Although lead was listed in Appendix A of the preamble to the rule as a class B2 carcinogen, no action level had been calculated because neither a carcinogenic slope factor (SF) nor a reference dose (RfD) had been developed by the Agency. Although the guidance in Appendix D of the proposed Corrective Action rule remains in effect with respect to other hazardous constituents, this directive now allows for the development of the lead screening ("action") level using the IEUBK model.

Recent developments (1992-Present). Following discussions among senior Regional and OSWER management, the OSWER Soil Lead Directive Workgroup (composed of Headquarters, Regional and other Federal agency representatives) recommended in the spring of 1992 that a "two step" decision framework be developed for establishing cleanup levels at sites with lead-contaminated soils. This framework would identify a single level of lead in soils that could be used as either the PRG for CERCLA site cleanups or the action level for RCRA Corrective Action sites, but would also allow site managers to establish site-specific cleanup levels (where appropriate) based on site-specific circumstances. The IEUBK model would be an integral part of this framework. OSWER then developed a draft of this directive which it circulated for review on June 4, 1992. The draft set 500 ppm as a PRG and an action level for RCRA facilities in residential settings.

Following development of this draft, OSWER held a meeting on July 31, 1992 to solicit a broad range of views and expertise. A wide range of interests, including environmental groups, citizens and representatives from the lead industry attended. This meeting encouraged OSWER to think more broadly about how the directive would affect urban areas, how lead paint and dust contribute to overall risk, and how blood lead data could be used to assess risk. In subsequent meetings with the Agency for Toxic Substances and Disease Control (ATSDR) and the Centers for Disease Control (CDC), options were discussed on how to use blood lead data and the need to evaluate the contribution of paint. In addition, during these meetings, a "decision tree" approach was

accomplish two objectives: (1) account for the contribution from multiple media to total lead exposure; and, (2) provide a stronger scientific basis for determining a soil lead cleanup level at a specific site.

Development of the IEUBK Model for OSWER use. During the 1989-91 time period, use of the EPA IEUBK model was identified as the best available approach for accomplishing the objectives outlined in the August 1991 guidance. The model integrates exposure from lead in air, water, soil, dust, diet, and paint with pharmacokinetic modeling to predict blood lead levels in children (i.e., children 6 to 84 months old), a particularly sensitive population.

In the spring of 1991, OSWER organized the Lead Technical Review Workgroup to assist Regional risk assessors and site managers in both using the model and making data collection decisions at CERCLA and RCRA sites. The workgroup was composed of scientists and risk assessors from the Regions and Headquarters, including the Office of Research and Development (ORD), and the Office of Pollution Prevention and Toxic Substances (OPPTS).

In November 1991, the EPA Science Advisory Board (SAB) reviewed the scientific merits of using the IEUBK model for assessing total lead exposure and developing soil lead cleanup levels at CERCLA and RCRA sites. In general, the SAB found the model to be an important advance in assessing potential health risks from environmental contaminants. However, the SAB also recommended additional guidance on the proper use of the model.

In response to SAB concern over the potential for incorrect use of the model and selection of inappropriate input values both for default and site-specific applications, OSWER developed a comprehensive "Guidance Manual for the Integrated Exposure Uptake Biokinetic Model for Lead in Children" (referred to in this interim directive as the "Guidance Manual"). This Guidance Manual assists the user in providing inputs to the model to estimate risks from exposures to lead. It discusses the use of model default values or alternative values, and the application of the model to characterize site risks. Use of the Guidance Manual should facilitate consistent use of the IEUBK model and allow the risk assessor to obtain valid and reliable predictions of lead exposure. The Lead Technical Review Workgroup has been collecting data to further validate the model and to update the Guidance Manual as needed.

Relationship to RCRA Corrective Action "Action" Levels. The approach for calculating a screening level for lead (including exposure assumptions), set forth in this Revised Interim Soil Lead Directive, supersedes the guidance provided for calculating

suggested that proposed different threshold levels (primary and secondary) for screening decisions, action decisions and land use patterns.

Findings from the three cities (Baltimore, Boston, and Cincinnati) of the Urban Soil Lead Abatement Demonstration Project (peer review scheduled for completion in late 1994) indicate that dust and paint are major contributors to elevated blood lead levels in children. Furthermore, preliminary findings suggest that any strategy to reduce overall lead risk at a site needs to consider not only soil, but these other sources and their potential exposure pathways. (For further information on this demonstration project, contact Dr. Rob Elias, USEPA/ORD, Environmental Criteria and Assessment Office (ECAO), RTP, (919) 541-4167.)

Finally, in its efforts to develop this interim directive, the OSWER Soil Lead Workgroup has met with other EPA workgroups including the TSCA Section 403, Large Area Lead Sites, and Urban Lead workgroups, as well as other Federal agencies including the Agency for Toxic Substances and Disease Registry, the Centers for Disease Control, and the Department of Housing and Urban Development.

Derivation of Lead Screening Levels. Development of the residential screening level in this interim directive required two important OSWER decisions. 1) OSWER determined that it would seek to achieve a specific level of protectiveness in site cleanups; generally, OSWER will attempt to limit exposure to soil lead levels such that a typical (or hypothetical) child or group of similarly exposed children would have an estimated risk of no more than 5% of exceeding the a 10 µg lead/dl blood lead level. This 10 µg/dl blood lead level is based upon analyses conducted by the Centers for Disease Control and EPA that associate blood lead levels of 10 µg/dl and higher with health effects in children; however, this blood lead level is below a level that would trigger medical intervention. 2) In developing the residential screening level, OSWER has decided to apply the EPA's IEUBK model on a site-specific basis. This model has been designed specifically to evaluate exposures for children in a residential setting. Current research indicates that young children are particularly sensitive to the effects of lead and require specific attention in the development of a soil screening level for lead. A screening level that is protective for young children is expected to be protective for older population subgroups.

In general, the model generates a probability distribution of blood lead levels for a typical child, or group of children, exposed to a particular soil lead concentration and concurrent lead exposures from other sources. The spread of the distribution reflects the observed variability of blood lead